IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO PLAINTIFFS: **All Wave II TVT Cases** **All Wave II Gynemesh Cases** **Bonnie Maxwell vs. Ethicon** **Case No. 2:12-cv-02138** **Karen Swanson vs. Ethicon** **Case No. 2:12-cv-01709**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL OPINION TESTIMONY OF ROBERT M. ROGERS, M.D.

I. PRELIMINARY STATEMENT

Now come Plaintiffs seeking to exclude, or to limit in the Court's discretion, the expert testimony of Dr. Robert M. Rogers, M.D. ("Dr. Rogers"), pursuant to Federal Rule of Evidence ("Rule") 702 and the standards set forth by the United States Supreme Court in *Daubert v. Merrell Dow Pharms. Inc.* 509 U.S. 579 (1993) and as adopted by the Fourth Circuit. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs the admissibility of expert testimony). Dr. Rogers seeks to offer general opinions regarding certain products manufactured and marketed by Defendant Ethicon, Inc. ("Ethicon") for the treatment of pelvic organ prolapse ("POP"), including Gynemesh PS. His opinions are proffered in the Gynemesh PS Expert Report

of [Dr. Rogers] ("Rogers Gynemesh Report")[1] and in his deposition testimony of June 16, 2016 regarding Gynemesh.

Dr. Rogers also seeks to proffer general opinions regarding the TVT manufactured and marketed by Ethicon for the treatment of SUI. Dr. Rogers's opinions are set forth in the TVT Expert Report of [Dr. Rogers] ("Rogers TVT Report")[2] and in deposition testimony of June 16, 2016 regarding the TVT.[3] Plaintiffs move now to limit some of Dr. Rogers's opinions regarding Ethicon's SUI devices as more fully set forth herein. In particular, Dr. Rogers cannot support his opinions regarding the TVT based solely in his experience with other Ethicon sling devices. In addition, Dr. Rogers offered testimony during both of his depositions and in both the Rogers Gynemesh Report and the Rogers TVT Report that Ethicon was acting as a "good company." Such opinions are subject to exclusion under applicable law.

II. LEGAL STANDARD

Rule 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702.

The Supreme Court in *Daubert* assigned to district courts a "gatekeeping function" in determining whether expert testimony is both reliable and relevant and, thus admissible, under

[1] The Rogers Gynemesh Report is attached hereto as Exhibit A. Citations to the Rogers Gynemesh Report are in the form (Ex. A, ___.)

[2] The Rogers TVT Report is attached hereto as Exhibit B. Future references to it will be in the form (Ex. B, ___.).

[3] Relevant excerpts of Dr. Rogers's deposition of June 16, 2016 regarding the TVT are attached hereto as Exhibit C. Citations to it will be in the form (Ex. C, ___:___.).

Rule 702. 509 U.S. 579. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)("Under [Rule] 702, trial judges act as gatekeepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable,") (internal citations and quotations omitted.). Under both *Daubert*, 509 U.S. 579, and Rule 104(a) -- the statute imposing a duty on courts to decide preliminary questions regarding the qualifications of witnesses and/or the admissibility of evidence -- this Court must determine whether the requirements of Rule 702 are met before any expert testimony can be presented to the jury. *See, Cooper*, 259 F.3d at 199; (the district court determines whether the methodology employed by the expert is "scientifically valid" and whether that methodology is applicable to the facts in issue). While *Daubert* requires Rule 702 to be applied flexibly, unfettered admissibility is not the standard and "the proponent of the testimony must establish its admissibility by a preponderance of proof." *See Cooper*, 259 F.3d at 199 (citing to *Daubert*, 509 U.S. at 592 n. 10; *see also Hines v. Wyeth*, C. A. No. 2:04-0690, 2011 WL 2792436 at *2 (S.D.W.Va. July 14, 2011).).

III. LEGAL ARGUMENT

A. DR. ROGERS'S GENERAL OPINIONS MUST BE LIMITED TO THE SCOPE OF HIS EXPERT REPORT AND HIS DEPOSITION TESTIMONY.

As this Court has previously held, an expert should not be allowed to testify "outside the scope of [his] expert opinion." *See Huskey v. Ethicon*, C. A. No. 2:12-cv-05201, 2014 WL 3861778 at *5 (S.D.W. Va. August 6, 2014). Dr. Rogers's two general reports are clearly limited in scope to opinions regarding two products manufactured and marketed by Ethicon: the Gynemesh P.S. and the TVT. (*See* Ex. A.) (*See also* Ex. B.) Any opinions he purports to give outside that scope should be excluded. Likewise to be excluded are any opinions on the TVT or Gynemesh that are not based in Dr. Rogers's experience.

For example, Plaintiffs now seek to exclude any and all opinions that Dr. Rogers seeks to offer about cadaver studies conducted by Ethicon concerning the TVT since Dr. Rogers admitted that he had no knowledge of those studies, if any, were even conducted by Ethicon:

> A. Well, I was asked - - I was not involved in the development of the retropubic TVT, but I was involved with the development of the TVT-O, transobturator TVT and TVT Secur, and Ethicon asked me to perform anatomic dissections to look at the anatomy to be sure that the passage of the instruments and the helical capacitor and the tape, and the mesh tape, to be sure that they would be in places that would not compromise nerves or tissue or - - you know.
>
> Q. Do you know if the same work was done for the TVT retropubic for which you offer an opinion today?
>
> A. I was not involved with that work and I don't know what was done specifically in that regard.
>
> Q. Do you know whether or not cadaveric work was done in connection with the TVT retropubic?
>
> A. I did such work at Jefferson Medical College on my own for my own learning not with Ethicon.
>
> * * *
>
> Q. Okay. And because of [the fact he had not seen any Ethicon documents indicating that consultants had done cadaver studies at the TVT] with respect to the TVT retropubic, if they did cadaveric studies, one, you're not sure if they did or not, and, two, you don't know whether it was on embalmed or unembalmed cadavers, correct?
>
> A. That's correct.

(Ex. C, 58:15-59:17.)(*See also Id.* 60:23-61:3.)(Q. "Do you know or have you undertaken any work to understand whether or not in fact cadaveric training was offered to physicians that desired to learn how to use the TVT device? A. The traditional TVT retropubic? I have no knowledge of that.").

In short, Plaintiffs now move to exclude any and all opinions Dr. Rogers purports to offer about the efficacy of the TVT ostensibly grounded in his cadaver studies of devices other than the TVT because such are not relevant to the TVT. Also to be excluded are any and all opinions that Dr. Rogers seeks to proffer about 1) the efficacy of the TVT devices that are grounded in Ethicon's cadaver studies of the TVT if any such exist, or 2) whether the cadaver studies Ethicon ostensibly offered were appropriate because Dr. Rogers has no knowledge of those studies whatsoever, to the extent they occurred at all. (*See e.g.*, Ex. C, 61:4-64:22.)

Likewise, Dr. Rogers may not opine on the clinical efficacy of the TVT device based on his experience implanting the TVT-O and TVT-Secur because such are beyond the scope of his present opinion. (*Id.*, 64:13-22.) He also may not offer opinions regarding the reliability of those non-TVT devices because they are similarly beyond the scope of his opinion in this case. *See Huskey*, 2014 WL 386 1778 at *5 (an expert may not testify outside the scope of his opinion.).

B. DR. ROGERS'S OPINION THAT ETHICON BEHAVED ADMIRABLY OR AS A "GOOD" COMPANY MUST BE EXCLUDED AS HIGHLY IRRELEVANT, HAVING PREJUDICIAL VALUE THAT EXCEEDS HIS OPINIONS' PROBATIVE EFFECT, AND INADMISSIBLE CHARACTER EVIDENCE.

This Court has previously signaled that it might be willing to exclude evidence that a corporate defendant was a "good company" since it is highly irrelevant, having prejudicial value that exceeds the opinions' probative effect and is inadmissible character evidence as long as plaintiffs provide specific examples of the evidence to be excluded. *See e.g., Holcomb v. Boston Scientific Corp.*, C. A. No. 2:12-cv-06302, 2016 WL 2962222 at *4 (citing Federal Rules of Evidence 401-404)(the court reserving judgment on whether evidence of defendant's "good acts" should be excluded since plaintiff provided no specific examples but still strongly implying that such might be excluded under Rules 401-404.). Plaintiffs now move to exclude the following testimony of Dr. Rogers on this ground:

- that between the late 1970's and 2007 when he was asked to assist Ethicon regarding the design and performance of its devices:

> I found that at Ethicon all my contacts, discussions and work with the research scientists, biomedical engineers and clinicians were consistently respectful, appreciated, and honest. The work environment attitude was always one of 'How can we best help the patient with this problem and eliminate any and all risks and potential complications." I never felt pressure to push a product out. All the product development I which I was involved was thoroughly evaluated and reevaluated step by step, in accordance to the Ethicon standards, the industry standards, and of course, the FDA and federal government standards.[4] There was no room for 'fudging' or manipulating data;

(Ex. A, 7; Ex. B, 5)

- that the development of Ethicon's products was "in earnest" and "with the patients' best interests always at the top of each agenda;" (Ex. A, 8; Ex. B, 6) and

- that Ethicon's efforts were "sincere" and "thorough;" (Ex. A, 9; Ex. B, 6.)

IV. CONCLUSION

For reasons of the forgoing, the general opinions of Dr. Roberts, as set forth herein, must be limited to the scope of his expert report and his deposition testimony as required by federal law.

Date: July 21, 2016

By: /s/ Fidelma L. Fitzpatrick

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[4] Additionally, Dr. Rogers is not qualified to offer opinion on corporate, government, or regulatory standards and his opinions regarding such should be excluded on that ground as well. *See* Rule 702.

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